DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 28, 2015

Captiva Spine
Rich Jansen, Pharm. D.
Silver Pine Consulting
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K142586
Trade/Device Name: Captiva Spine FuseLOX Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: April 28, 2015
Received: April 29, 2015

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(If known)*
K142586

Device Name
FuseLox Cervical IBF System

Indications for Use *(Describe)*
The Captiva Spine FuseLOX Cervical IBF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. FuseLOX Cervical IBF implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autogenous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation.

Type of Use *(Select one or both, as applicable)*
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: April 28, 2015
Submitter: Dale Mitchell
Captiva Spine
967 Alternate A1A #1
Jupiter, FL 33477
877-772-5571
866-318-3224

Device: Captiva Spine FuseLOX Cervical IBF System
Product Class: Class II
Classification: 888.3080 Intervertebral Body Fusion Device
Product Codes: ODP
Panel Code: 87

Reason for this Submission:
This Traditional 510(k) is to introduce the Captiva Spine FuseLOX Cervical IBF System manufactured from PEEK-OPTIMA™ LT1.

Predicate Device(s):

The Captiva Spine FuseLOX Cervical IBF System is substantially equivalent to the previously cleared primary predicate Transcorp ACIF System found in K092794.

Device Descriptions:
The Captiva Spine FuseLOX Cervical IBF System includes various size implants manufactured from implant grade PEEK-OPTIMA™ LT1 conforming to ASTM F2026-12. The devices also have radiopaque markers made from either titanium alloy (Ti6Al4V) per ASTM F136 or tantalum per ASTM F560-08. The implant is hollow to allow for autogenous bone graft material. The implant is provided non-sterile.

Indications for Use:
The Captiva Spine FuseLOX Cervical IBF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. Captiva Spine FuseLOX Cervical implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autogenous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation.

Intended Use:
The Captiva Spine FuseLOX Cervical IBF is intended to provide mechanical support of the cervical spine while biologic fusion occurs. It is intended to be used with supplemental fixation.

Performance Standards:
Captiva Spine FuseLOX Cervical IBF System was evaluated to demonstrate equivalence to the predicate device. Mechanical testing, which characterized the mechanical performance and fatigue endurance to show the original performance requirements for Static Compression, Static Compression Shear, Static Torsion, Dynamic Torsion, Expulsion, Dynamic Compression, and Dynamic Compression Shear per ASTM F2077-11 were met. No clinical testing was performed.

Conclusion:
The results of non-clinical testing demonstrate that the design, function, intended use, and indications for use of the Captiva Spine FuseLOX Cervical IBF System is substantially equivalent to the predicate and raises no new questions of safety or effectiveness.